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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,707	12/23/2005	Patrice Mauriac	207,381	8596
7590 03/11/2011				
Jay S Cinamon Abelman Frayne & Schwab 10th Floor 666 Third Avenue New York, NY 10017			EXAMINER AZPURU, CARLOS A	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 03/11/2011	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/562,707

**Applicant(s)**

MAURIAC ET AL.

**Examiner**

Carlos A. Azpuru

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 34-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-942)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date 04102006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of the information disclosure statement filed 04/10/2006.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 24-33 and 37-40 in the reply filed on 12/29/2010 is acknowledged. The traversal is on the ground(s) that the claims entail a single inventive entity. This is not found persuasive because the claims of Group II include a bioactive not found in the claims of Group I. Further, this additional step changes the classification of the invention from Class 428 (which is for the particle) to that of a drug delivery particle which is found in Class 424. Even without the additional search and examination burden, the inventive concept changes with the addition of the bioactive principle steps found in Group II.

The requirement is still deemed proper and is therefore made FINAL.

Claim 34- 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/29/2010. Please note that claim 37 was originally set out as part of Group I. However, claim 37 sets out the addition of an "active principle".

Therefore, the claims elected for examination of this invention are claims 24-33.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants set out a ration in claim 24(d), however it is indefinite as to what the ratio is referring to other than PLGA. The same ration is is further limited in claim 33. Further clarification is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24 - 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tjila et al(Us Patent No. 5,520,923) in view of Chen et al (WO 03/041685).

Tjila et al disclose microparticle formulations which are manufactured using a lower alkyl alcohol, preferably ethanol (see Col. 2, lines 55-56). PLGA is specifically recited at col. 3, lines 29-40. Particle diameters are listed at col. 3, lines 41-51 and include 250  $\mu\text{m}$ . Heating of the Solvent and particles is done at a temperature of 45 to 60 C (see col. 5, lines 3-23). The product is then cooled to 4 C (see column 2, lines 24-27, reading on claim 1 of the instant invention). Steps e) – g) are not required steps. Alcohol amounts are listed for the undried particle as 50% -100%. Therefore the dried product would be expected to have final values close to those instantly claimed. While claim 37 refers to extrusion to shape the particles, the instant method uses molds to form the same particles. Further, Tjila et al use a circulating water bath to dry the mixture, however this is an art recognized variant which produces the same results. Tjila et al differs in that the amount of ethanol set out is higher than instantly claimed.

However, in the particulate system set out by Chen et al, the amount of ethanol is set out as a range of between 0.01 to 15% weight percent. As such, those of ordinary skill would have found it well within their skill to claim the instant particle given the teachings of Tjila et al which set out PLGA particles using an ethanol solvent, in view of Chen et al which uses the claimed range of ethanol in such particle systems. The instant particle would have been obvious to one of ordinary skill in the art at the time of invention given the teachings of Tjila et al in view of Chen et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1617

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